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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,603	04/28/2006	William Suttle Peters	13634.4010	3360
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ORRICK, HERRINGTON & SUTCLIFFE, LLP			EXAMINER	
IP PROSECUTION DEPARTMENT			PORTER, JR, GARY A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,603	Applicant(s) PETERS, WILLIAM SUTTLE
	Examiner GARY A. PORTER, JR	Art Unit 3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 October 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-10 and 15-23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/GS-68)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date: _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding Claim 1, Applicant claims "a first end external to the patient" and "a second end implanted in the patient." Applicant has claimed the human body with these limitations, which is non-statutory.

Claims 2-10 are rejected as being dependent on non-statutory Claim 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Freed et al. (US Patent 6,132,363).

4. Regarding claims 1, 15 and 16, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Freed teaches a percutaneous gas-line for a medical device, the gas-line including a first gas-line part 28 capable of being wholly implanted, due to its size, in a patient and having a first end capable of sealing a connection to the medical device and a second end with a connection fitting (Fig. 1); and a second gas-line part 18 capable of being part-implanted and part-external and having a first (external) end capable of sealing a connection to an external driver (col. 4, lines 34-35; Fig. 1) and a second (implanted) end capable of removably sealing a connection with the connection fitting 16 on the second end of the first gas-line part (Fig. 1,4; col. 4, lines 28-35; col. 9, lines 45-54). Furthermore, although Freed teaches the connection 12 between first 28 and second 18 gas line parts is partially external and partially internal (Fig. 3, 4), the Examiner notes the connection of the first gas line part 28 and second gas line part 18 is capable of being fully positioned within the body due to its size and is therefore is "positionable fully within the body. Lastly, Freed teaches a subcutaneous anchoring collar, i.e. flange at base 16, that covers a short section of internal gas line 28 (col. 14, lines 28-25; Fig. 5) and is positioned "about the second gas-line" when the second gas line is connected to the first gas line.

5. In regards to claims 2 and 17, Freed teaches the second gas-line part is further capable of being removed for replacement. This capability is shown by the detachable connection of the second gas-line part 18 to implanted connector 12 (Fig. 4)
6. With regards to claim 3, Freed teaches the first (external) end of the second gas line is removably connected to the external driver (col. 4, lines 34-35).
7. In regards to Claims 4 and 18, Freed teaches an ECG lead 30 implanted in a patient's epicardium (col. 4, lines 20-27; col. 9, lines 45-54). Freed further discloses that ECG lead 30 is connected the drive unit 14 and that external line 18 is the only line connecting connector 16 to drive unit 14. As such, the ECG lead 30 must be incorporated into line 18 in order to establish connection with the drive unit (Fig. 3 and 5; col. 4, lines 20-26).
8. Regarding Claims 5 and 19, Freed discloses the gas line is small in diameter, i.e. 5 mm, is kink resistant (col. 4, lines 10-15), and is flexible (col. 4, lines 29-31).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6-8, 10, 20, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freed et al. (US Patent 6,132,363).

11. Regarding Claim 6, Freed discloses a gas line that is positionable within the human body in order to support a patient's cardiovascular function (Abstract). Freed also discloses that the internal gas line 28 has a diameter of 5 mm (col. 4, lines 16-20). Although Freed does not disclose the exact dimensions of the external line 18, one can ascertain that gas line 18 and 28 are of relatively the same diameter (Fig. 1 and 4). Given that the size of the second gas-line part 28 has a diameter close to that of the internal part, i.e. 5 mm, it would have been an obvious matter of design choice to alter the diameter of the second gas-line part to be 7 mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

12. In regards to Claims 7 and 20, Freed discloses that the first gas line part 28 is wholly implanted and the second gas-line part 18 is capable of being implanted due to its dimensions and is connected to first gas-line part via connector 16. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a biocompatible and biostable material for the construction of second gas line part 18, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

13. In regards to Claims 8 and 21, Freed discloses all of the claimed invention except for the exact material composition of the gas line. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ silicone 45-

65A durometer for the construction of second gas line part 18, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

14. With regards to Claims 10 and 23, Freed discloses a cloth covered collar, i.e. flange at base 16 that covers a short section of internal gas line 28 (col. 14, lines 28-25; Fig. 5). Freed does not disclose that the collar material is a "fluffy polyester." However, the Examiner notes that Applicant has not assigned any criticality to this material nor has Applicant cited any unexpected results of using the material within the specification. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyester as the cloth collar, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

15. Claims 9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freed et al. (US Patent 6,132,363) in view of Fleenor et al. (5,814,012) and Foster et al. (5,290,249). Freed discloses all of the claimed invention except for a Luer-lock fitting as the gas-tight connection fitting. Instead, Freed discloses a snap on button-type connection fitting (Fig. 3, 4). However, the Examiner notes that Applicant has not assigned any criticality to the type of fitting used nor has Applicant disclosed any unexpected results from using the Luer-lock fitting as the specific gas tight fitting. It

appears that as long as the connection is a removable connection (non-permanent connection) and is gas-tight, it would be suitable for the current invention. Furthermore, the Examiner notes that Luer-locks are often used when making gas-tight connections between different sections of tubing (Fleenor, col. 4, lines 37-58; Foster, col. 5, lines 1-14).

16. Given that Luer-locks are a generally known means for creating a gas-tight seal between two components, the Examiner contends that it would have been obvious for one of ordinary skill in the art to try this type of connection in lieu of the snap connector of Freed in order to create a gas-tight seal since it would perform the same function as that of the snap connector, which is to create a removable gas-tight seal.

17. Additionally, with regards to creating a gas-tight fitting between two sections of tubing, Fleenor at col. 4, lines 37-58 and Foster at col. 5, lines 1-14 demonstrate that Luer-locks are equivalent structures known in the art for making a removable gas-tight seal between two components and one of ordinary skill in the art would have found it obvious to replace the Luer-lock for the snap connector of Freed.

Response to Arguments

18. Applicant's arguments filed 10/06/2009 have been fully considered but they are not persuasive.

19. Applicant argues at page 8 in the Remarks section that "the second gas-line part referred to by the Examiner is only external to the patient and not part-implantable within the patient's body and part-external to the patient's body as claimed." Applicant

further argues that "the PAD 12 is clearly not 'positioned fully within the body of the patient in spaced relation with an exit site in the body of the patient through which the second gas-line part is adapted to pass' as claimed." The Examiner respectfully disagrees.

20. The claims presented by Applicant are a system claim not a method claim. In system claims, the prior art of record only has to have the capability of performing the functionality claimed by Applicant. Therefore, the terms "implantable" and "positionable" only require that the invention of Freed be capable of being implanted or positioned in the manner claimed by Applicant, which as stated in the rejection above, the Freed reference is necessarily capable of doing.

21. If Applicant believes the exact configuration of the portions of the device are the novel portions of Applicant's invention (this appears to be the case since Applicant is arguing the specific configuration of the device with respect to the human body), then the Examiner suggests writing a method claim set that incorporates the intended configuration listed in Claim 1. The Examiner notes, however, that the method must be commensurate in scope with system Claims 1 and 15. If it is not, the new claim set would be treated as an election by original presentation. In other words, the method claims would be treated as a non-elected invention and would be withdrawn from the current application. See MPEP §821.03.

22. If Applicant wants to pursue the system as the patentable invention, the Examiner suggests more clearly reciting structural elements that make the device "implantable" and "positionable" in the manner recited in Claim 1. As claimed currently,

Freed discloses the same structure that, due to its size, is certainly capable of being "implantable" and "positionable" in the manner claimed by Applicant.

23. Lastly, Applicant states that "the preamble to the claim recites an implantable medical device implanted in the body of a patient and including a percutaneous gas line must be given effect as a meaningful limitation in claims 14-23, and, thus, it is submitted that the casting of these claims in Jepson form removes any vestige of doubt about the inapplicability of Freed to the claimed inventions." The Examiner respectfully disagrees. Freed discloses a percutaneous gas line that is connected to an implanted medical device, i.e. blood pump 10 (Fig. 1). The claimed invention and Freed are commensurate in scope.

24. As noted above, the differences Applicant points out between the claimed invention and the prior art pertain more to the method of implanting and configuring the device than the actual structural components. Since the novelty of Applicant's invention appears to lie in the configuration during implantation and use of the invention, a method claim would be more suitable. Otherwise, Applicant needs to incorporate more specific structure that illustrates how the device is configured in the manner described.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY A. PORTER, JR whose telephone number is (571)270-5419. The examiner can normally be reached on Monday - Thursday, 7AM - 4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. A. P./
Examiner, Art Unit 3766

/Carl H. Layno/
Supervisory Patent Examiner, Art
Unit 3766